FEB 2 0 2004

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K033731.

Submitter Information

Address:	Fujirebio Diagnostics, Inc. 201 Great Valley Parkway Malvern, PA 19355
Contact person:	Kimberly Peterson, (610) 240-3828
Summary preparation date:	November 26, 2003

Name of Device

Trade/Proprietary Name:	AxSYM® Cortisol assay
Common/Usual Name:	Cortisol Assay
Classification Name:	Cortisol (hydrocortisone and hydroxycorticosterone) test system

Predicate Device

Beckman Access® Cortisol assay

Device Description

The AxSYM Cortisol assay utilizes Fluorescence Polarization Immunoassay (FPIA) technology. The AxSYM Cortisol Reagents and sample are pipetted in the following sequence:

- Sample and all AxSYM Cortisol Reagents required for one test are pipetted by the sampling probe into various positions of a Reaction Vessel (RV).
- Sample, the Cortisol Antiserum (antibody), pretreatment solution and Solution 4 (Line Diluent) are pipetted into one well of the RV.
- Additional pretreatment solution and Solution 4 (Line Diluent) are pipetted to the cuvette of the RV.

- The RV is immediately transferred into the Processing Center. Further pipetting is done in the Processing Center by the Processing Probe.

In the processing center, an aliquot of the predilution mixture and Solution 4 (Line Diluent) are transferred to the cuvette of the RV and the blank intensity of the sample is measured. A second aliquot of the predilution mixture is transferred to the cuvette along with the Cortisol Fluorescein Tracer. Cortisol from the sample and the Cortisol Fluorescein Tracer compete for binding sites on the antibody molecule. The intensity of polarized fluorescent light is measured by the FPIA optical assembly.

Intended Use

The AxSYM® Cortisol assay is a Fluorescence Polarization Immunoassay (FPIA) for the quantitative measurement of Cortisol in human serum, plasma or urine on the AxSYM® System to aid in the diagnosis and treatment of adrenal disorders.

Summary of Performance characteristics

Reproducibility:

Precision was determined as described in the National Committee for Clinical Laboratory Standards (NCCLS) Protocol EP5-A. Three buffer-based panel members (1, 2, and 3) were assayed, in replicates of two, at two separate times per day, for 20 days. Three reagent lots were tested using two instruments, with a single standard calibration per reagent pack. The total precision was determined by calculating the standard deviation (SD) and percent coefficient of variation (%CV) values for each sample.

The total precision %CV of the AxSYM® Cortisol assay was determined to be less than or equal to 15.0.

Comparison Study

A total of 130, endogenous and cortisol-spiked serum and sodium heparin plasma specimens and 150, endogenous and cortisol-spiked urine specimens were tested using the AxSYM Cortisol assay and a Competitor Cortisol assay. Least squares and Passing-Bablok linear regression analyses were performed on all specimens with concentration values within the dynamic range of both assays (0 – 60µg/dL for the both the AxSYM and the Competitor Cortisol assays).

Least squares linear regression analysis comparing the AxSYM® Cortisol assay to the Beckman Access® Cortisol assay for serum and plasma yielded a correlation coefficient of 0.96, a slope of 0.87 and Y-axis intercept of - 0.74. Least squares linear regression analysis for urine yielded a correlation coefficient of 0.98, a slope of 0.79 and Y-axis intercept of - 0.59.

Passing-Bablok linear regression analysis comparing the AxSYM Cortisol assay to the Beckman Access Cortisol assay for serum and plasma yielded a correlation coefficient of

0.96, a slope of 0.93, and Y-axis intercept –2.39. Passing-Bablok linear regression analysis for urine yielded a correlation coefficient of 0.98, a slope of 0.79, and Y-axis intercept –0.48.

Expected Values:

A study was conducted to establish the normal range for a given population using the AxSYM® Cortisol assay. A total of 50 serum (AM and PM collections) and 49 urine (24 hour collection) specimens from apparently healthy individuals were evaluated using the AxSYM® Cortisol assay.

In the population tested, the 95% confidence limit for the normal range of AM and PM cortisol in the serum specimens was determined to be 4.2 to 38.4 µg/dL (median value 10.8 µg/dL) and 1.7 to 16.6 µg/dL (median value 6.7 µg/dL) respectively. It is recommended that each laboratory establish its own range.

The 95% confidence limit for the normal range of cortisol in urine specimens was determined to be 32 to 243 µg/24 hour (median value 88 µg/24 hours). It is recommended that each laboratory establish its own range.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 2 0 2004

Ms. Kimberly M. Peterson
Manager, Regulatory Affairs
Fujirebio Diagnostics, Inc.
201 Great Valley Parkway
Malvern, PA 19355

Re: k033731
Trade/Device Name: AxSYM® Cortisol assay
Regulation Number: 21 CFR 862.1205
Regulation Name: Cortisol (hydrocortisone and hydroxycorticosterone) test system
Regulatory Class: Class II
Product Code: JFT; JIT; JJX
Dated: November 26, 2003
Received: December 15, 2003

Dear Ms. Peterson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Jean M. Cooper MS, DVM.

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K033731

Device Name: AxSYM® Cortisol assay

The AxSYM® Cortisol assay is a Fluorescence Polarization Immunoassay (FPIA) for the quantitative measurement of Cortisol in human serum, plasma or urine on the AxSYM® System to aid in the diagnosis and treatment of adrenal disorders.

✓ prescription

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurence of CDRH, Office of Device Evaulation (ODE)

(Optional Format 3-10-98)

Carol C Benson

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K033731